UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): June 24, 2024

EDESA BIOTECH, INC.

(Exact Name of Registrant as Specified in its Charter)

British Columbia, Canada	**001-37619**	**N/A**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Spy Court
Markham, Ontario, Canada L3R 5H6
(Address of Principal Executive Offices)

(289) 800-9600
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
Common Shares	EDSA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD.

On June 24, 2024, Edesa Biotech, Inc. (the "Company" or "Edesa") issued a press release announcing that its drug candidate, paridiprubart ("EB05"), has been selected by the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, for evaluation in a U.S. government-funded clinical study. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission (the "SEC"), and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of

1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On June 24, 2024, the Company announced that its drug candidate, paridiprubart ("EB05"), has been selected by the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, for evaluation in a U.S. government-funded clinical study.

Paridiprubart represents a new class of host-directed therapeutics ("HDTs") that are designed to modulate the body's own immune response when confronted with known or unknown public health threats such as pandemic influenza, COVID-19, other emerging infectious diseases, and chemical, biological, radiological, and nuclear incidents. Importantly, HDTs are agnostic to the causal agent and can be stockpiled preemptively to respond to public health emergencies and biodefense.

The BARDA-funded Phase 2 platform trial will be a randomized, double-blinded, placebo-controlled, multi-center U.S. clinical trial to investigate three novel threat-agnostic host-directed therapeutics, including EB05, in hospitalized adult patients with Acute Respiratory Distress Syndrome ("ARDS") due to a variety of causes. The BARDA study of EB05 is expected to build on the success of a Phase 2 clinical study that the Company completed during the COVID-19 pandemic which demonstrated that paridiprubart reduced mortality by 84% among critically ill ARDS patients. A parallel study using an *in vitro* model also demonstrated that EB05 inhibits a key mediator of inflammatory responses from influenza and other pathogens. A separate Edesa-sponsored Phase 3 study of EB05 in patients with ARDS due to SARS-CoV-2 infection is currently ongoing in Canada and the U.S.

The BARDA-funded study will be managed under a BARDA contract with PPD Development, LP, a clinical research business of Thermo Fisher Scientific, Inc. For the EB05 cohort of the study, patients will be randomized one-to-one to either EB05plus Standard of Care ("SOC") or to a placebo plus SOC control arm. The Company will provide drug products to the study as well as technical support.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated June 24, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Edesa Biotech, Inc.

Date: June 24, 2024

By: */s/ Stephen Lemieux*
Name: Stephen Lemieux
Title: Chief Financial Officer

BARDA Selects Edesa Biotech's Drug for U.S. Funded Platform Trial in General ARDS

- *This Phase 2 clinical study will evaluate paridiprubart (EB05) in hospitalized patients with acute respiratory distress syndrome (ARDS) due to a variety of causes.*
- *This BARDA-funded project is expected to complement Edesa's ongoing drug development activities in COVID-19 ARDS.*
- *Paridiprubart was selected following a competitive review process of multiple host-directed therapeutic candidates.*

Toronto, ON / ACCESSWIRE / June 24, 2024 / Edesa Biotech, Inc. (Nasdaq:EDSA), a clinical-stage biopharmaceutical company focused on developing host-directed therapeutics (HDTs) for immuno-inflammatory diseases, announced today that its first-in-class drug candidate has been selected by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, for evaluation in a U.S. government-funded clinical study.

Edesa's drug paridiprubart represents a new class of HDTs that are designed to modulate the body's own immune response when confronted with known or unknown public health threats such as pandemic influenza, COVID-19, other emerging infectious diseases, and chemical, biological, radiological, and nuclear incidents. Importantly, HDTs are agnostic to the causal agent and can be stockpiled preemptively to respond to public health emergencies and biodefense.

"HDTs have the potential to become key countermeasures for both critical care medicine as well as pandemic preparedness and biodefense, and we are pleased to be part of public-private efforts to speed the development of novel therapeutics that are threat-agnostic and can be rapidly deployed to protect civilian and military populations," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech.

The BARDA-funded Phase 2 platform trial will be a randomized, double-blinded, placebo-controlled, multi-center U.S. clinical trial to investigate three novel threat-agnostic host-directed therapeutics, including paridiprubart, in hospitalized adult patients with ARDS. The BARDA study of paridiprubart is expected to build on the success of a Phase 2 clinical study that the company completed during the COVID-19 pandemic which demonstrated that paridiprubart reduced mortality by 84% among critically ill ARDS patients. A parallel study using an *in vitro* model also demonstrated that paridiprubart inhibits a key mediator of inflammatory responses from influenza and other pathogens. A separate Edesa-sponsored Phase 3 study of paridiprubart in patients with ARDS due to SARS-CoV-2 infection is currently ongoing in Canada and the U.S.

Dr. Nijhawan said that the data from the BARDA-run study, which includes an exploratory biomarker study, could provide additional support and insight for expanding the utility of paridiprubart. "We expect this parallel study to inform our development, regulatory, and commercialization plans. Our ultimate goal is to label paridiprubart as a standard-of-care drug therapy for all-cause ARDS," he said.

The BARDA-funded study will be managed under a BARDA contract with PPD Development, LP, a clinical research business of Thermo Fisher Scientific, Inc. For the paridiprubart cohort of the study, patients will be randomized one-to-one to either paridiprubart plus Standard of Care (SOC) or to a placebo plus SOC control arm. Edesa will provide drug products to the study as well as technical support. Additional details regarding this trial can be found on the BARDA website.

About ARDS

Acute Respiratory Distress Syndrome manifests in some patients as an exaggerated immune response leading to inflammation and injury to the lungs that prevents the lungs from oxygenating blood and ultimately deprives the body of oxygen. For moderate to severe cases, there are currently few recommended treatments other than supplemental oxygen and mechanical ventilation, and mortality rates are high. In addition to virus-induced pneumonia, ARDS can be caused by smoke/chemical inhalation, sepsis, chest injury, and other causes. Prior to the pandemic, ARDS accounted for 10% of intensive care unit admissions, representing more than 3 million patients globally each year.

About Paridiprubart

Paridiprubart is a first-in-class human monoclonal antibody developed for acute and chronic disease indications that involve dysregulated innate immune responses. This host-directed therapeutic candidate inhibits toll-like receptor 4 (TLR4), a key immune signaling receptor that has been shown to be activated both by viruses, like SARS-CoV-2, SARS-CoV-1, and influenza, as well as in the pathogenesis of chronic autoimmune diseases.

About Edesa's Phase 3 Clinical Study

Edesa's Phase 3 study of paridiprubart is a multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of paridiprubart in critical-care patients. The current protocol will recruit ARDS subjects hospitalized with SARS-CoV-2 infections who are on invasive mechanical ventilation, both with and without additional organ support. The primary endpoint of the trial is the mortality rate at 28 days.

About Edesa Biotech, Inc.

Edesa Biotech, Inc. (Nasdaq: EDSA) is a clinical-stage biopharmaceutical company developing innovative ways to treat inflammatory and immune-related diseases. The company's most advanced drug candidate is paridiprubart (EB05), a monoclonal antibody developed for acute and chronic disease indications that involve dysregulated innate immune responses. Edesa is currently evaluating paridiprubart (EB05) in a Phase 3 study as a potential treatment for ARDS, a life-threatening form of respiratory failure. In addition, Edesa is developing an sPLA2 inhibitor, EB01 (daniluromer), as a topical treatment for

chronic allergic contact dermatitis (ACD), a common occupational skin condition. The company has also received regulatory approval to conduct a Phase 2 trial of its EB06 monoclonal antibody as a treatment for vitiligo, a life-altering autoimmune disease that causes skin to lose its color in patches. Edesa is also planning to file an investigational new drug application for a future Phase 2 study of paridiprubart (EB05) for pulmonary fibrosis. Sign up for news alerts. Connect with us on X (Twitter) and LinkedIn.

Edesa Forward-Looking Statements

This press release may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "plan," "estimate," "expect," "intend," "may," "will," "would," "could," "should," "might," "potential," or "continue" and variations or similar expressions, including statements related to: the company's belief that the BARDA study could provide additional support and insight for expanding the utility of EB05; the company's expectation that the BARDA study will inform Edesa's development, regulatory and commercialization plans; the company's goal of labeling EB05 as a standard-of-care drug therapy for all-cause ARDS; and the company's timing and plans regarding its clinical studies in general. Readers should not unduly rely on these forward-looking statements, which are not a guarantee of future performance. There can be no assurance that forward-looking statements will prove to be accurate, as all such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results or future events to differ materially from the forward-looking statements. Such risks include: the ability of Edesa to obtain regulatory approval for or successfully commercialize any of its product candidates, the risk that access to sufficient capital to fund Edesa's operations may not be available or may be available on terms that are not commercially favorable to Edesa, the risk that Edesa's product candidates may not be effective against the diseases tested in its clinical trials, the risk that Edesa fails to comply with the terms of license agreements with third parties and as a result loses the right to use key intellectual property in its business, Edesa's ability to protect its intellectual property, the timing and success of submission, acceptance and approval of regulatory filings, and the impacts of public health crises, such as Covid-19. Many of these factors that will determine actual results are beyond the company's ability to control or predict. For a discussion of further risks and uncertainties related to Edesa's business, please refer to Edesa's public company reports filed with the U.S. Securities and Exchange Commission and the British Columbia Securities Commission. All forward-looking statements are made as of the date hereof and are subject to change. Except as required by law, Edesa assumes no obligation to update such statements.

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